UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION	)	**3:09-MD-02100-DRH-CJP**
	)	**MDL No. 2100**
	)	**Honorable David R. Herndon**
This Document Relates to:	)	
ALL Cases	)	

MEMORANDUM IN SUPPORT OF MOTION OF COOPERATING PLAINTIFFS' COUNSEL FOR APPOINTMENT OF AN ORGANIZATIONAL TEAM

I. Introduction

Movants and the firms supporting this Memorandum[1] collectively represent over 1,500 women who have suffered serious personal injury and in some tragic instances wrongful death due to ingestion of the hormonal birth control products, Yasmin and Yaz. The injuries alleged include serious blood clots causing deep vein thrombosis and pulmonary embolism, as well as strokes and heart attacks. In addition, an alarming number of young women have suffered severe gall bladder complications due to Yasmin and Yaz, often requiring surgery for gall bladder removal. While such injuries historically have been related to high dose birth control pills, and specifically to the first generation birth control products sold in the 1960s, reduction in the doses of the active hormone ingredients over the decades in the formulations commonly referred to as the "second generation" pills has protected women from these serious adverse effects without lessening product efficacy. Regretfully, as the patents have expired on the safer, second

[1] The total number of firms between Movants and supporting firms is 35. For a list of those firms see Supplemental Motion to Appoint Interim Liaison Counsel for Plaintiffs and Response to Related Pleadings at pp. 6-9. Doc. 12.

generation birth control pills, drug companies have developed third generation, and now with the advent of Yasmin and Yaz, fourth generation pills. These third and fourth generation pills place women at greater risk of serious injury than the second generation products, and serve no purpose but to increase drug company profits.

Yaz and Yasmin are the most popular and widely prescribed name brand combination oral contraceptives in the United States, ranking as the 28th and 56th highest selling drugs in 2008 respectively. They are manufactured and distributed by Bayer Corporation and its subsidiaries. Bayer has achieved its dominant market position in part through direct to consumer advertisements in which Bayer touted the benefits of Yasmin and Yaz compared to other birth control pills. The FDA, however, disagreed with the accuracy of Bayer's representations and mandated sanctions, including a corrective advertising campaign to recant Bayer's superiority claims. *See* Ex. A. In addition, the FDA recently determined in an inspection of Bayer's manufacturing facilities in Germany that manufacturing standards for Yasmin and Yaz were not being met, and listed several deficiencies, including the release of drugs that were out of specification. *See* Ex. B. In addition, in 2009 two major studies were published in the British Medical Journal documenting a statistically significant increase in the risk of venous thrombotic events with Yasmin and Yaz as compared to second generation birth control pills. *See* Ex. C. Yet the public remains largely unaware of these risks, and millions of women continue to use these products when safer and cheaper alternatives are readily available.

II. Early action to organize the litigation is essential to protect the interests of the parties and ease the burden on the Court.

The *Manual for Complex Litigation, Fourth* recognizes that early efforts by the Court to structure and organize complex litigation best serves the interests of all parties. *Manual* at §10.11. In implementing this important early involvement, the Manual notes, "The attorneys -

who will be more familiar than the judge with the facts and issues in the case - should play a significant part in developing the litigation plan and should have primarily responsibility for its execution." *Id.* at §10.13. Obviously, the first order of business in developing a litigation plan is to appoint counsel to act on behalf of plaintiffs. Once that order is in place, many other tasks must be addressed immediately by appointed counsel. Through early organization, Plaintiffs' Counsel can assist the Court and the Defendant in managing resources and avoiding unnecessary disputes. As will be set forth at length below, the group of attorneys proposed to be in the leadership comprise a substantial number of experienced firms who are already familiar with the scientific and medical issues because they have been actively involved in leading a different successful MDL involving similar issues – *In re Ortho Evra Products Liability Litigation*, MDL No. 1742 (N.D.Ohio) – in front of the Judge David Katz of the Northern District of Ohio.

Movants anticipate numerous preliminary matters which must be addressed efficiently and immediately to protect the interests of all plaintiffs. These responsibilities include development of document requests and interrogatories to defendant; negotiation of a plaintiff fact sheet (customarily adopted in lieu of interrogatories and document requests to plaintiffs), as well as negotiation of a defendant fact sheet (customarily used to obtain case specific information from defendants); negotiation of a protective order; negotiations to permit direct filing of cases in the transferor court; negotiation of a non-destruct order; negotiation of a stipulation concerning the format of the document production (i.e. requirements for searchable documents and metadata, agreements regarding production of computerized data and internal sharedrives, etc.); preparation of a proposed order concerning financing on behalf of plaintiffs; preparation of a proposed order concerning compensation for common benefit work; and negotiations for

procedures to coordinate the litigation with anticipated state court actions.[2] In addition, counsel for plaintiffs must track the cases filed, be familiar with the injuries alleged, and implement procedures to be sure that the MDL is developing evidence to prove the injuries claimed, or to notify individual counsel if they have alleged a unique issue.

In addition to the preliminary procedural matters, Counsel for Plaintiffs also must conduct an extensive review of the scientific literature and begin identifying experts in many scientific and medical fields (such as epidemiology, pharmacology, hematology, neurology, gastroenterology, good manufacturing practices, and FDA regulations, to name a few). When the document production begins, Plaintiffs' Counsel must organize an effective and efficient process for the review of millions of pages of information from Defendants and maintain a secure document depository for all Plaintiffs to use and thus not burdening the Defendant with multiple production of documents. Plaintiffs also anticipate the need for skilled brief writers with expertise in the law regarding pharmaceutical torts, including such issues as *Daubert*, learned intermediary and preemption.[3] All of these tasks require a team of lawyers working in concert to whom responsibilities can be assigned and divided. These tasks also require substantial financial resources.

Moreover, unlike many MDLs that involve primarily a single liability issue, the claims involving Yasmin and Yaz present significant liability issues in at least three areas,

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[2] As the Court may be aware, a consolidated proceeding is underway in state court in Pennsylvania concerning the Yasmin and Yaz products liability claims. In addition, it is anticipated at a minimum that some type of coordination will be forthcoming for cases filed in New Jersey and in California. Coordination of activities between the federal court proceedings and state court is often requested by Defendants in mass tort litigation, and early communication with state court judges is desirable.

[3] In fact, recent case law developing concerning preemption in the context of generic drugs will undoubtedly be raised as cases involving Ocella (the generic form of Yasmin) are ultimately transferred to this Court. *See e.g. Mensing v. Wyeth, Inc.*, No. 08-3850 (8th Cir. Dec. 10, 2008), on appeal from *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056 (D. Minn. 2008).

manufacturing, marketing and defective product. In many past multidistrict actions, just one of these areas of inquiry alone has supported multidistrict consolidation. For example, the Digitek MDL and the Sulzer Hip MDL only involved manufacturing issues. The *In re Bayer Corp. Combination Aspirin Products Marketing and Sales Litigation*, MDL No. 2023, E.D.N.Y. only involved claims of over promotion and false marketing. The Diet Drugs MDL focused on defective product claims for Fen Phen, including causation and failure to warn. Each of these litigations nonetheless required the best efforts of many plaintiff firms appointed by the MDL transferor courts. However, the issues in the Yasmin and Yaz litigation are not isolated to a single liability theory, but instead encompass each of these three areas. Movants therefore submit that an experienced and comprehensive organizational team will be essential to protect the interests of plaintiffs.

III. Movants are well qualified counsel with specific experience in hormonal birth control litigation.

Besides their vast experience in successfully representing plaintiffs in a myriad of pharmaceutical and medical device mass torts, Movants have spent significant time developing expertise specific to the issues in this litigation. In particular, Movants herein include counsel who have represented women in the Ortho Evra litigation, in which they successfully resolved thousands of cases involving claims of deep vein thrombosis, pulmonary embolism, stroke and heart attack caused by an allegedly defect hormonal birth control patch. Movants include Lead and Liaison Counsel for the Plaintiffs in the Ortho Evra MDL, as well as members of the Plaintiffs' Steering Committee and Discovery Committee in the Ortho Evra MDL Litigation. Other Movants served as lead counsel in the Ortho Evra proceedings coordinated in California state court. *See* Ex. D.

Through their work in the Ortho Evra litigation, Movants have become well versed in the history and science of hormonal contraceptives, medical issues concerning coagulopathy, and the pharmacologic and epidemiologic issues concerning adverse events related to prescription hormonal products. Among their many achievements in Ortho Evra, counsel reviewed over 15 million pages of documents concerning venous thrombotic events and hormonal contraceptives, deposed scores of corporate employees, and analyzed decades of medical literature, product labels and FDA regulations concerning hormonal birth control. Counsel developed highly credentialed experts on behalf of plaintiffs, and made presentations to the Court during an educational hearing known as Science Day. Movants who acted as presenters for the Plaintiffs at Science Day are Janet Abaray, who presented experts in pharmacology and epidemiology, and Gary Douglas, partner of Michael London, who presented experts in hematology. In addition, many other counsel included among Movants participated actively in the Ortho Evra litigation, including Roger Denton, who was a member of the Discovery Committee and took or defended dozens of depositions in the MDL and in state court litigation; Mark Robinson, who acted as lead counsel in the California Ortho Evra litigation, and Michael London, who served as MDL Liaison Counsel. Movants also prepared during the Ortho Evra litigation extensive evidence and research for *Daubert* motions involving the risks of venous thrombotic events from exposure to hormonal contraceptive products, and submitted comprehensive briefs on federal preemption.

Without exception, each of the proposed leadership firms has direct and extensive experience in pharmaceutical mass tort litigation. In addition to his work on Ortho Evra, proposed Liaison Counsel Roger Denton and his firm also serves as Liaison Counsel for plaintiffs in the Nuva Ring MDL litigation,[4] which is a hormonal contraceptive vaginal ring

[4] *In Re: Nuva Ring Product Liability Litigation*, 4:08-MD-1964 RWS (E.D.Mo). *See* Ex. E.

product also alleged to cause venous thrombotic adverse events. As a result, the Schlichter firm has the experience and infrastructure available to operate a national document depository located within 10 minutes of this courthouse. Others of the Movants have served in leadership roles in litigation concerning hormone replacement therapy as a treatment for menopause, and in early litigation involving high dose hormonal contraceptive pills sold in previous decades. Movants include counsel who acted as lead counsel, liaison counsel, executive committee or steering committee members in the multidistrict litigation involving Vioxx, Kugel Mesh, Ephedra, Gadolinium, Diet Drugs, PPA, Heparin, Levaquin and a host of other major litigations. Courts recognize that experience in the legal issues involved in the litigation is the "most persuasive" factor in appointing counsel for plaintiffs. *See In re: Terazosin Hydrochloride*, 220 F.R.D. 672, 702 (S.D. Fla. 2004); *In re Cardinal Health Inc.*, 225 F.R.D. 552 (S.D.Ohio 2005). Clearly the Counsel proposed herein have a wealth of relevant experience.

It should also be noted that Movants, and the firms supporting them, represent over 1,500 clients with signed fee agreements and are investigating thousands of more claims. The firms that support this motion use due care in screening cases including reviewing medical records and do not simply "rush" to file a case. Movants did not just start working on the Yasmin and Yaz litigation last week, or last month. To the contrary, Movants have been involved in representing victims of Yasmin and Yaz for many months, and as such have had ample opportunity to meet, share ideas and organize on behalf of Plaintiffs in this litigation. Movants also actively participated in the motions and arguments before the Judicial Panel on Multidistrict Litigation, including Roger Denton who filed pleadings and presented oral argument supporting that this Court be assigned this MDL. Such consistent commitment to the case is a recognized qualification for selecting firms to act as leaders in the litigation. *See Cardinal Health*, 225

F.R.D. at 556. Movants are also able to make the financial commitment necessary to pursue this litigation. Consideration of the adequacy of the resources of counsel is appropriate and necessary when appointing leadership in complex litigation. *See Manual for Complex Litigation* at §10.221.

In fact, Counsel herein became alert to problems with Yasmin and Yaz years ago, when in developing the case against Johnson & Johnson in the Ortho Evra MDL, information that had been developed in that litigation indicated that Yasmin and Yaz had a very alarming rate of reported thromboembolic injuries to the FDA. As claimants alleging serious personal injury from Yasmin and Yaz came forward, Counsel within the undersigned group discussed the topic at a mass torts conference held over a year ago. Since then, careful evaluation of the claims has been undertaken, including a review of the public available adverse event reports and other FDA information, as well as scientific literature that supports the claims made in this litigation. Thereafter, a group of counsel including many firms herein held a meeting in Denver in April of 2009 to discuss the liability issues, the science and organization of counsel. Ultimately, a consensus was reached that plaintiffs would be well served by formation of a multidistrict proceeding, and various venues were offered by the undersigned counsel as appropriate options to suggest to the JPML. On the evening prior to the JPML argument, a meeting was held in which all counsel involved in the federal court cases already filed or with a known interest in the litigation were invited to attend. While determination of plaintiffs' leadership necessarily depended upon the decision of the JPML and the Orders of the transferor court, nonetheless counsel for plaintiffs were united in their desire to support well-qualified and experienced counsel appropriate to the litigation and to this venue.

The group of attorneys before this Court on this pleading are uniquely qualified to lead the Yasmin and Yaz MDL litigation. Movants and their supporting firms currently represent over 1,500 hundred injured women and have vast experience in pharmaceutical litigation and specific experience in litigation regarding hormonal contraceptive products. By appointing counsel with such credentials and backgrounds, the Court will benefit the plaintiffs as a whole, and will reduce the risks, expense and time needed to develop the claims in this litigation because substantial related work has already been developed in the Ortho Evra MDL. In addition, the Defendant and hopefully the Court will find that the experience of Plaintiffs' Counsel is an asset in managing this complex litigation.

IV. The Need For Designation Of Liaison Counsel And Permanent Counsel Before The Initial Case Management Conference

In order for an effective Initial Case Management Conference to be successfully conducted, particularly due to the evolving state court litigation, Liaison Counsel must be appointed to coordinate a number of preliminary administrative matters that are best addressed in advance of the Conference. These matter include: (a) a proposed agenda for the conference; (b) a broad description of the claims; (c) the procedural status of the litigation, including the status of motions and state-court related litigation; (d) a preliminary estimate of the number of cases that may become part of the MDL; (e) the content of a proposed Case Management Order addressing issues such as establishment of a document repository and agreement on a document production format; (f) submission of a list of all counsel of record and their contact information; (g) the use of medical releases and fact sheets; (h) suggestions on the content of potential preservation and protective orders; and (i) whether the appointment of a Special Master is appropriate for any functions pursuant to Fed. R. Civ. P. 53(1)(A&C).

Certain Plaintiffs' firms have moved the Court to defer the appointment of Liaison Counsel until the Court's initial status conference. Notably, none of these firms have expressed that the Schlichter Firm is not qualified to serve as Liaison Counsel. Despite the assertions in these motions, effective organization and coordination among counsel is critical at the outset of the litigation because of the nature of the preliminary matters that are to be addressed in advance of an Initial Case Management Conference, and appointment of organizational leadership therefore should *not* be deferred until after the initial conference.

A deferral of the appointment of leadership is not in the best interest of the parties. Deferring appointment of leadership would prevent Plaintiffs from coordinating the preliminary matters discussed above and would lead to an ineffective initial conference. Timely appointment of leadership is necessary to ensure orderly communication among involved parties, including those Plaintiffs' firms that have not yet entered an appearance in the MDL. As noted in the *Manual for Complex Litigation, Fourth*, "[t]he [initial] conference is not a perfunctory exercise, and its success depends on establishing effective communication and coordination among counsel and between counsel and the court." *See* §11.211 of the *Manual for Complex Litigation, Fourth*. The Honorable Judge Eldon Fallon of the Eastern District of Louisiana recognized the importance of early appointment of Liaison Counsel in the *In re Vioxx Product Liability Litigation*. In that recent pharmaceutical products liability MDL, Judge Fallon entered an order the day after the JPML Transfer Order was issued, directing plaintiffs' counsel to confer and seek consensus on the selection of a candidate for the position of liaison counsel (subject to court approval). *See In re: Vioxx Product Liability Litigation*, MDL No. 1657, *MDL Transfer Order*, issued Feb. 16, 2005 (attached as Ex. F) and *Pretrial Order No. 1*, issued Feb. 17, 2005 (attached

as Ex. G)[5]. In another pharmaceutical products liability MDL, the Honorable Judge Ann Aldrich of the Northern District of Ohio also appointed interim liaison counsel as the court's first order of business prior to the initial conference. *See In Re: Oral Sodium Phosphate Solution-Based Prods. Liab. Litig.*, MDL No. 2066, *Pretrial Order No. 1*, (N.D. Ohio, Jul. 16, 2009) (attached as Ex. H).[6] Pursuant to §11.12 of the *Manual for Complex Litigation, Fourth*, this Court has authority, even *sua sponte*, to initiate special procedures at the outset of the case pending the initial conference including appointing liaison counsel. *See also Federal Judicial Center's Manual for Complex Litigation*, 4th ed. 2004 §10.221 (outlining the responsibilities of liaison counsel).

Furthermore, appointment of "co-liaison" counsel does not promote efficiency and organization. The appointment of a single liaison counsel has been approved in other pharmaceutical products liability MDLs and no authority is cited for the concept of a mandatory "dual" liaison counsel. For example, the Honorable Judge James Carr of the Northern District of Ohio's Order appointed a single Interim Liaison Counsel prior to the Initial Status Conference in the Heparin products liability MDL. *In Re: Heparin Prods. Liab. Litig.*, MDL Docket No. 1953, *Order* (N.D. Ohio Jun. 17, 2008) (attached as Ex. I). Similarly, the Honorable Judge Harvey Bartle of the Eastern District of Pennsylvania appointed single interim counsel in the Diet Drugs product liability litigation. *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, *Pretrial Order No. 3* (E.D. Pa. Jan. 9, 1998) (attached as Ex. J).[7]

[5] Counsel is aware of this Court's instruction regarding avoiding citations to other U.S. District Court cases as authority for a particular proposition of law. These citations are not cited as binding precedent on this Court, but only as a practical source of representative orders entered by other courts addressing a similar issue in multidistrict litigation.
[6] *See* Footnote 5.
[7] *See* Footnote 5.

Furthermore, approval of a permanent structure for the plaintiffs' before the initial status conference will allow the Court to focus on the litigation and not any remaining disagreements between a few dissenting counsel. Furthermore, to have a procedure whereby the Court would "interview" counsel (which has been suggested by one firm) is not an efficient use of the Court's time and would delay the progress of this litigation. If the Court desires a process, then a very short opportunity can be given to any dissenting firms, limited to written argument and should be presented promptly. This Court can then decide on a structure before the initial case management conference.

V. Counsel appointed to act for Plaintiffs must be professional and cooperative.

It is axiomatic that all counsel in federal court are expected to display the highest degree of professionalism. However, as noted in the *Manual for Complex Litigation*, "The added burdens and demands of complex litigation place a premium on attorney professionalism, and the judge should encourage counsel to act responsibly." *Manual for Complex Litigation* at §10.21 Such responsibility must include a sincere effort to avoid burdening the Court with unnecessary issues that counsel should be able to resolve through courtesy and communication. The Manual notes:

> Counsel need to fulfill their obligations as advocates in a manner that will foster and sustain good working relations among fellow counsel and with the court. They need to communicate constructively and civilly with one another and attempt to resolve disputes informally as often as possible.

Manual for Complex Litigation at §10.21.

The undersigned counsel have followed this mandate by working together to agree on a proposal for management of this litigation. Indeed, Movants have sought to avoid burdening the Court with intramural activities regarding organization. Despite the best efforts of Movants a few firms have dissenting views, but Movants will continue efforts to attempt resolutions.

In fact, Movants have made efforts to communicate with objecting firms in an attempt to reach agreement or compromise and have in fact been able to resolve most of these matters without the need for Court action. Yet despite Movants' best efforts at inclusion and cooperation, a few firms – involving firms who had not filed any cases until after the MDL was assigned to this Court – simply have demonstrated a determination to be uncooperative and disruptive. But these firms are by far the exception. The remainder of the plaintiffs' bar enjoys the camaraderie of joining forces on behalf of plaintiffs.

Because the vast majority of firms are interested in protecting their clients, working together, sharing resources and avoiding duplicative effort, there has been little problem in reaching agreement as to a proposed leadership structure. The firms supporting this application seek to have their clients represented by experienced, competent counsel who excel in the area of pharmaceutical torts. They support counsel with the highest ethical standing, outstanding courtroom achievements, superior academic backgrounds and proven records of success. They support appointment of counsel who can work with other firms and who will act in the best interests of the clients. They support counsel who are familiar with the science and the legal issues presented, rather than counsel who are unfamiliar with issues involving hormonal birth control litigation. They want counsel who can honor the financial commitments necessary to prepare a complex pharmaceutical mass tort. They want counsel who will be respected by their opponents and respected by this Court and who will work as part of a comprehensive team to protect the interests of the clients.

The coordinated and cooperating Plaintiffs' Counsel therefore support the following counsel for leadership positions in this litigation. While the proposed structure may be somewhat larger than the Court would otherwise envision, Counsel points out that this litigation

is quite complex, and presents three major liability avenues that will require significant work and expertise. Because the experienced Plaintiffs' counsel herein recognize the complexities of this case and anticipate the highly competent defense likely to be put forth by Bayer's counsel, Movants suggest an inclusive structure through which plaintiffs can benefit from each firm's expertise.

As such, Plaintiffs propose as follows:

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Further, the proposed Plaintiffs' Executive Committee and the Plaintiffs' Steering Committee have the support of many firms across the country in managing this litigation given the track record of the firms that make up these proposed Committees. For instance, many well-qualified firms from around the country have contacted members of this proposed leadership group expressing an interest in working on various discovery committees. One of the first tasks of the Executive Committee and the Steering Committee is to assemble a Discovery Committee that will be responsible for working on discovery related issues and developing this case.

In addition to the individual attorneys listed above, the lead firms have already committed significant resources investigating these claims and intend to commit significant numbers of senior and experienced attorneys, staff and money as needed to prosecute this claim. From Schlichter, Bogard and Denton, this includes Jerome Schlichter, Kris Kraft, Beth Wilkins as well as an organized support staff to act as liaison counsel and to manage the document depository. From Burg, Simpson, Eldridge, Hersch & Jardine, this includes Mike Burg, Seth Katz, Calvin Trege and additional staff who successfully litigated Ortho Evra as lead counsel. From Levin, Papantonio, Thomas, Mitchell, Echsner, & Proctor, P.A this includes Mike Papantonio and Tim O'Brien and their firm of established lawyers in pharmaceutical litigation. From Douglas & London, this includes Gary Douglas and Michael London who bring a wealth of experience in mass tort litigation. These combined firms with their experiences and resources present an outstanding group to lead this litigation. Furthermore, all of the firms on the various committees have well-qualified and experienced attorneys dedicated to the successful prosecution of this litigation. The firms in this proposed structure represent the best of the best of the plaintiffs' bar involved in pharmaceutical litigation, reaching from all parts of the country.

VI. CONCLUSION

It is respectfully suggested that given the magnitude of this MDL, and that other state court proceedings are already underway, that it is important for this Court to act swiftly in approving an organizational structure for Plaintiffs, as well as setting an initial case management conference. The organizational structure needs to be in place before the initial conference so that discussion can be had with defense counsel on an agenda and agreements on preliminary organized case management. As pointed out in Bayer's pleadings, an initial case management conference needs to be set soon.

Respectfully Submitted,

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I hereby certify that on the 22nd day of October, 2009, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System which will send notification of such filing to the following:

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